DEPARTMENT OF HEALTH & HUMAN SERVICES

COPY

Public Health Service

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
P.O. Box 3012
Bothell, WA 98041-3012

Telephone: 425-486-8788
FAX: 425-483-4996

November 24, 1998

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 99-03

Andrea Wahry, President
Trapper's Creek, Inc.
5650 B Street
Anchorage, Alaska 99518

WARNING LETTER

Dear Ms. Wahry:

On August 17 and 18, 1998, an investigator from the Food and Drug Administration (FDA) conducted an inspection of Copper River Smoking Company, located at 724 First Street, Mukilteo, Washington. At the conclusion of the inspection Barney V. Alanis, Operations Manager, was presented with a FORM FDA 483 listing serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (HACCP Regulation). A copy of that FORM FDA 483 is enclosed for your review. By virtue of these deficiencies the hot smoked, vacuum packaged, refrigerated salmon, processed at your facility is adulterated within the meaning of Section 402(a)(4) of the Food, Drug, and Cosmetic Act (the Act) and 21 CFR Part 123. 21 CFR Part 123.16 requires processors of smoked fishery products to include in their HACCP plans how they are controlling the food safety hazard associated with the formation of toxin by *Clostridium botulinum* for at least as long as the shelf life of the product under normal and moderate abuse conditions.

Specifically, our investigator found the following deficiencies, related to hot smoked, vacuum packaged, refrigerated salmon.

1. Your firm has not adequately established that its process will consistently provide a finished product water phase salt (wps) of 3.5% or higher, which is necessary to control the growth of *Clostridium botulinum.* This was evidenced by the [redacted] sample test report from March 1, 1998, where the wps was only 3.3%. Only one sample of your product was analyzed for wps after a reported procedural change in your brining process after the March 11, 1998 analysis. 21 CFR Part 123.8(a) requires you to verify that your HACCP plan is adequate to control food safety hazards that are reasonably likely to occur.

2. Your firm did not identify the food safety hazard of *Clostridium botulinum* toxin formation during finished product storage, and therefore had not established finished product storage as a critical control point. 21 CFR Part 123.6(c)(1) requires you to list, in the HACCP plan, all food safety hazards that are reasonably likely to occur. Once a food safety hazard is identified, 21 CFR Part 123.6(c)(2) requires you to list the critical control points for each identified hazard.

3. There is a temperature monitoring system which provides temperature readings each half hour on each [redacted] probes. One of the probes [redacted] is in the smokehouse and measures the internal flesh temperature of the fish that is being smoked. This is how your firm was monitoring the critical limit of the flesh temperature [redacted] for a minimum of [redacted] minutes. On July 3, 1998, an alarm report indicated that the [redacted] probe was malfunctioning. Therefore, since that time, and at least up until the time of the inspection, the probe provided unreliable readings. No corrective action was recorded as being taken. When your firm began to take the temperature manually, your firm actually changed the monitoring procedure for the cooking critical control point, and thus, under 21 CFR Part 123.8(a)(1), you should have modified your HACCP plan. Additionally, you were not maintaining records of the manual temperature monitoring, as required by 21 CFR Part 123.6(c)(7).

4. The HACCP plan did not list verification procedures, such as calibration and record review. 21 CFR Part 123.6(c)(6) requires you to list verification procedures, and the frequency thereof, that the processor will use in accordance with 21 CFR Part 123.8(a).

5. Monitoring records were not signed and dated as being reviewed. 21 CFR Part 123.8(a)(3) requires the review, including signing and dating, of critical control point monitoring records, by a HACCP trained official.

6. Prevention of cross contamination and protection from adulteration, two of the eight elements of sanitation, were not being monitored. 21 CFR Part 123.11(b)&(c) require you to monitor and record the monitoring and corrective action for the conditions and practices related to the eight elements of sanitation. During the previous inspection of your firm in January of 1998, and in the resulting untitled letter, similar sanitation monitoring deficiencies were brought to your attention. Though your firm has made some correction in the area of sanitation monitoring, you continue to lack in monitoring all elements of sanitation.

The above HACCP violations are not meant to be an all-inclusive list of deficiencies in your plant. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Pertinent sections of the Act and the Regulations are enclosed for your review. Your reply relating to these concerns should be addressed to the Food and Drug Administration, Attention: Janelle K. Main, Compliance Officer, P.O. Box 3012, Bothell, Washington, 98041-3012.

Sincerely,

Roger L. Lowell
Seattle District Director

Enclosures:
FORM FDA 483
Section 402 of the Act
21 CFR Part 123

cc: With Disclosure Statement
WSDA